DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JUL 27 2015

MSI MedServ International Deutschland GmbH
Ms. Christine Strobel
Managing Director
Escad Strasse 3
D-88630 Pfullendorf
Germany

Re: K083840
Trade/Device Name: MSI MedServ International – Rigid Endoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCM
Dated (Date on orig SE ltr): September 11, 2009
Received (Date on orig SE ltr): September 11, 2009

Dear Ms. Strobel,

This letter corrects our substantially equivalent letter of September 28, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

SEP 11 2009

510(k) Number (if known): K 083840

Device Name: MSI MedServ International - Rigid Endoscope

K-40

Indications for Use: Rigid Endoscopes

MSI MedServ International Deutschland GmbH rigid endoscopes and accessories is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs and canals.

Prescription Use X **AND/OR** **Over-The-Counter Use _____**
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083840

K083840

SEP 2 8 2009

Special 510(k) Notification

Section 4. 510(k) Summary

General Provisions	Submitter's Name and Adress	MSI MedServInternational GmbH Escad Str. 3 D-88630 Pfullendorf
	Contact Person	Mr. Karl-Heinz Puscher 49 7552-936-570 khpuscher@medservinternational.de
	Classification Name	Endoscopes and accessories
	Proprietary Name	MSI MedServInternational Rigid endoscopes
Name of Predicate Device	Predicate Device Olympus America Inc.	510 (k) Reference No. K950076
Device Description	A rigid endoscope is a tubular endoscopic device with any of a group of accessory devices which attach to the endoscope and is intended to provide access, illumination and allow observation or manipulation of body cavities, hollow organs, and canals. It is typically used with a Fiberoptic light source and carrier to provide illumination.	
Intended Use	The rigid endoscopes and accessories of MSI MedServ International Deutschland GmbH are devices used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs and canals.	
Summary of Technological Characteristics	The rigid endoscopes of MSI are similar in construction and materials to the previously cleared endoscope K950076 of Olympus, America.	
Summary of substantial equivalence	The rigid endoscopes of MSI are considered to be substantially equivalent to the currently marketed Olympus rigid endoscope based on a comparison of the intended uses, designs and results of the testing and evaluations performed.	